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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |  |
|-----------------------------|-------------|-----------------------|------------------------|------------------|--|
| 10/701,942                  | 11/05/2003  | Satish Ramanial Mehta | 0640/71389/JPW/AG 7133 |                  |  |
| 7590 01/19/2005             |             |                       | EXAMINER               |                  |  |
| John P. White               |             |                       | KUMAR, SHAILENDRA      |                  |  |
| Cooper & Dunh               | am LLP      |                       |                        |                  |  |
| 1185 Avenue of the Americas |             |                       | ART UNIT               | PAPER NUMBER     |  |
| New York, NY                | 10036       | 1621                  |                        |                  |  |
|                             |             |                       |                        |                  |  |

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Applica   | tion No.  | Applicant(s)   |                     |  |  |  |
|--|--|---|---|--|---------------------|--|--|--|
|  |  |   | 942   | MEHTA ET AL.   |                     |  |  |  |
|  | Office Action Summary  | Examin  | er  | Art Unit   |                     |  |  |  |
|  |  |   | NDRA - KUMAR  | 1621   |                     |  |  |  |
| Period fo  | The MAILING DATE of this communic<br>or Reply  | ation appears on t  | he cover sheet with the c   | correspondence ad  | ldress              |  |  |  |
| A SH<br>THE<br>- Exter<br>after<br>- If the<br>- If NO<br>- Failu<br>Any | ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNIC Insions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this communic period for reply specified above is less than thirty (30) operiod for reply is specified above, the maximum stature to reply within the set or extended period for reply within the set or extended period f | ATION.  37 CFR 1.136(a). In no ication.  days, a reply within the story period will apply and it. by statute, cause the a | event, however, may a reply be tin<br>tatutory minimum of thirty (30) day<br>will expire SIX (6) MONTHS from<br>pplication to become ABANDONE | nely filed<br>s will be considered timel<br>the mailing date of this o<br>D (35 U.S.C. § 133). | y.<br>ommunication. |  |  |  |
| Status   |  |   |   |  |                     |  |  |  |
| 1)   | Responsive to communication(s) filed   | on 05 November  | 2003.   |  |                     |  |  |  |
| 2a)□   |  |   |   |  |                     |  |  |  |
| 3)   |  |   |   |  |                     |  |  |  |
| -,-  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |   |  |                     |  |  |  |
| Dispositi  | ion of Claims  |   |   |  |                     |  |  |  |
| 5)□<br>6)⊠<br>7)□  | Claim(s) <u>1-8</u> is/are pending in the appleau of the above claim(s) is/are Claim(s) is/are allowed.  Claim(s) <u>1-8</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction   | withdrawn from o  |   |  |                     |  |  |  |
| Applicati  | on Papers  |   |   |  |                     |  |  |  |
| 9)   | The specification is objected to by the  | Examiner.   |   |  |                     |  |  |  |
| 10)  | 0) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |   |  |                     |  |  |  |
|  | Applicant may not request that any objection   | on to the drawing(s   | ) be held in abeyance. See  | e 37 CFR 1.85(a).  |                     |  |  |  |
|  | Replacement drawing sheet(s) including the   | •   | <del>-</del> , ,  |  |                     |  |  |  |
| 11)  | The oath or declaration is objected to b   | y the Examiner. I   | Note the attached Office  | Action or form PI  | O-152.              |  |  |  |
| Priority u   | ınder 35 U.S.C. § 119  |   |   |  |                     |  |  |  |
| a)[  | Acknowledgment is made of a claim fo  All b) Some * c) None of:  1. Certified copies of the priority do  3. Copies of the certified copies of application from the International cee the attached detailed Office action   | ocuments have be<br>ocuments have be<br>the priority docur<br>al Bureau (PCT R  | een received.<br>een received in Applicati<br>nents have been receive<br>ule 17.2(a)).  | on No ed in this National  | Stage               |  |  |  |
| Attack   | Wa)  |   |   |  |                     |  |  |  |
| Attachment   | t(s)<br>e of References Cited (PTO-892)  |   | 4) Interview Summary  | (PTO-413)  |                     |  |  |  |
| 2) 🔲 Notic   | e of Draftsperson's Patent Drawing Review (PTC   |   | Paper No(s)/Mail Da   | ite  | ,                   |  |  |  |
|  | nation Disclosure Statement(s) (PTO-1449 or PT<br>r No(s)/Mail Date <u>8/2/04</u> .  | O/SB/08)  | 5)  Notice of Informal P 6)  Other:   | atent Application (PTC   | D-152)              |  |  |  |

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# **DETAILED ACTION**

Claims 1-8 are pending in this application.

## **Priority**

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in India on 10/31/2003. It is noted, however, that applicant has not filed a certified copy of the Indian application as required by 35 U.S.C. 119(b).

#### Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 8/2/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

# Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims depict chlorohydrin as formula (5), however, there is no formula (5) found any where in claim 1, thus rendering these claims indefinite.

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04-198175 or JP 01-10272.

Instant claims are directed to a process of making atenolol, by reacting a phenol with epichlorohydrin in the presence of alkali metal hydroxide and a quaternary ammonium salt as phase transfer catalyst, wherein an intermediate glycidyl ether is formed, which is then reacted with isopropylamine to give atenolol.

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JP'175 or JP'272 teach a process of making atenolol, by reacting a phenol with epichlorohydrin in the presence of alkali metal hydroxide and a quaternary ammonium salt as phase transfer catalyst, wherein an intermediate glycidyl ether is formed, which is then reacted with isopropylamine to give atenolol, see English abstract of both the documents. Also see JP'175, page 527, compound (II), page 528, column 1, compound II-VI, and JP'072, page 567, column 1 and 2, compounds (1) to 3, page 568, column 1 and 2. The difference between the reference and herein claimed process appears to be the temperature range and may be amount of the reactants and catalyst.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the process of JP'175 or JP'272, to make atenolol, by reacting a phenol with epichlorohydrin in the presence of alkali metal hydroxide and a quaternary ammonium salt as phase transfer catalyst, wherein an intermediate alycidyl ether is formed, which is then reacted with isopropylamine, because the prior art is expressly teaching all the steps and the process is analogous with any difference if at all is with respect to the temperature range and amount of the reactants, which can be worked out under routine experimentation, with the reasonable expectation of achieving a high yield of purified atelonol, absent evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the 9. examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri. Application/Control Number: 10/701,942

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAILENDRA - KUMAR Primary Examiner

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S.Kumar 1/16/05